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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/443,982	05/18/95	DIXIT V	203442107020

HM22/0317

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EXAMINER	
ROMEO, D	
ART UNIT	**PAPER NUMBER**
1646	30

DATE MAILED: 03/17/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/443,982	Dixit et al.
Examiner: David S. Romeo 3/15/99	Group Art Unit: 1646

☒ Responsive to communication(s) filed on *12-17-98*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49, and 53-60* is/are pending in the application.

Of the above, claim(s) *53 and 59* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5, 21, 29, 30, 37-43, 45, 48, 49, 54-58, and 60* is/are rejected.

☒ Claim(s) *23 and 46* is/are objected to.

☒ Claims *1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49, and 53-60* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Newly submitted claim(s) 59 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method of claim 59 is independent or distinct from the methods originally claimed, because it uses different starting materials and/or process steps. Furthermore, the method of claim 59 can be practiced with another materially different product, such as an antibody that binds to the cytoplasmic domain of the Fas receptor.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim(s) 59 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claim 53 remains withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 25.

Formal Matters

3. This application contains claims 53 and 59 drawn to an invention nonelected by original presentation. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. The amendment filed 12/17/98 (Paper No. 29) has been entered in full. Claims 1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49, and 53-60 are pending. Claims 1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49, 54-58 and 60 are being examined.

5. Any objection or rejection of record that is not maintained in this Office action is withdrawn.

6. Figure 2C is objected to under 37 CFR 1.83(a) because it fails to show the arrow that is in the figure legend at page 4, lines 4-6.

Response to Arguments

7. The rejection of claim(s) 2, 29 and 30 under 35 U.S.C. § 112, first paragraph, is maintained. The rejection of record is applied to claims 57, 58 and 60. Applicants argue that the FADD protein of the instant invention is defined by structural characteristics and/or biologic

functions intrinsic to FADD and that someone who is designing a fragment or an analog of the FADD protein and wishes to determine wether such a fragment or analog falls within the scope of the claim can readily do so by comparing the sequence of the fragment with the sequences listed in the disclosure with reference to the limitations required by the claims. Applicants' arguments have been fully considered but they are not persuasive. There are no structural limitations to the claimed FADD protein in claim 2. Claim 2 encompasses all proteins with the recited molecular weight that have the recited functional activity, including species structurally unrelated to SEQ ID NO:2. A 23.3 kDa protein would contain approximately 200 amino acid residues. There are approximately 200^{20} proteins with molecular weights of 23,300. The specification has disclosed SEQ ID NO:2, fragments thereof, and an analog thereof having a single point mutation in SEQ ID NO:2. In the case of the claimed genus of proteins, encompassing proteins that are structurally unrelated to SEQ ID NO:2, the disclosure of SEQ ID NO:2, fragments thereof and an analog thereof having a single point mutation in SEQ ID NO:2. is insufficient to support such a broad claim because the specification does not provide guidance for obtaining structurally unrelated proteins having the desired activity. In the absence of such guidance the skilled artisan would have to resort to extensive experimentation wherein proteins are randomly assembled and through trial and error experimentation determine which have the desired activity. Such extensive, random, trail and error experimentation is considered undue. It is also likely that majority of the approximately 200^{20} proteins do not have the desired activity. Proteins are so precisely built that

the change of even a few atoms in one amino acid can disrupt the structure and cause a catastrophic change in function. See Alberts et al. (U3), page 119. The specification has not taught how to use a non-functional protein.

Furthermore, the claims are not limited to "the sequences listed in the disclosure". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. At page 13, lines 22 to 25, the specification defines FADD as a protein that modulates cellular function associated with Fas receptor pathway. At page 14, line 29 to page 15, line 7, the specification merely recites that a FADD protein can be a purified protein containing 208 amino acids and can have a particular molecular weight as characterized by SDS-PAGE. The definition of FADD provided by the specification is so broad that it is almost structurally limitless.

Claims 28 and 29 are directed to a method of screening for an agent that inhibits the binding of a FADD protein or polypeptide to the Fas receptor. However, there are no structural limitations to the "FADD protein or polypeptide", recited in claim 29, see especially lines 2 and 9, and in claim 30, see especially lines 2, 6 and 12. There are no structural limitations to the FADD recited in claim 58. Such FADDs encompass polypeptides that are structurally unrelated to those of the instant invention, as discussed above. Insofar as the specification has not enabled FADDs that are structurally unrelated to those of the instant invention then the specification has not enabled the methods of claims 29, 30, 57, 58 and 60. Claims 57, 58 and 60 also require that the

skilled artisan screen all conceivable cellular functions for modulation. The specification has only disclosed the induction of apoptosis. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor. Such a claim is *prima facie* not enabled. When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor.

MH 8. The rejection of claim(s) 45 under 35 U.S.C. § 112, first paragraph, is maintained. Applicants argue that the amendment was merely a correction of a typographical error. Applicants' arguments have been fully considered but they are not persuasive. The correction of a typographical error was not the basis of the rejection. The claim was rejected for reciting the limitation "having conservative amino acid substitutions at amino acids 1 to 120 and 122 to 208", because the specification does not appear to support the concept of conservative amino acid substitutions in the claimed mutein.

9. The rejection of claim(s) 1, 3-5, 21, 37-39, 41-43, 48, 49 and 54-56 under 35 U.S.C. § 112, second paragraph, over the recitation of "FADD" is maintained. The rejection of record is applied to claim(s) 2, 29, 30, 57, 58 and 60. Applicants argue that the definition of "FADD" is clearly specified at pages 13-14 of the disclosure. Applicants' arguments have been fully considered but they are not persuasive. The specification at page 14, full paragraph 2, intends the term "FADD" to include mammalian FADD proteins, as well as muteins, analogs and fragments thereof, anti-FADD antibodies and anti-idiotypic antibodies. The specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "FADD" and an artisan cannot determine what additional or material functional limitations are placed upon a claim by the presence of this element.

10. The rejection of claim(s) 3 and 37-43 under 35 U.S.C. § 112, second paragraph, is maintained. Applicants argue that SEQ ID NO:2 is recited in claim 1 to specify the sequence of amino acid residues. Applicants' arguments have been fully considered but they are not persuasive. The protein of claim 1 comprises the amino acid sequence of SEQ ID NO:2 or an analog thereof, and is open to the inclusion of other amino acid residues even in major amounts. A claim dependent on claim 1, wherein the dependent claim recites a specific amino acid sequence, such as "amino acid 24 to amino acid 208", is vague, indefinite and ambiguous in the absence of a sequence identifier, i.e. SEQ ID NO:, because it is unclear if the sequence is amino

acid 24 to amino acid 208 of SEQ ID NO:2. The metes and bounds of the claim(s) are not clearly set forth.

New Claim Objections

11. Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 57 recites the step of analysis "to determine how the agent modulates the cellular function regulated by the Fas receptor pathway". There is no earlier recitation of modulating the cellular function regulated by the Fas receptor pathway, and the inclusion of such a limitation broadens the scope of the parent claim and fails to further limit the parent claim.

12. The declaration filed on 12/17/98 under 37 CFR 1.131 is sufficient to overcome the rejection of claims 5, 46, 48, 55 and 56 over the Boldin et al. reference.

New Claim Rejections - 35 USC § 112

13. Claims 57, 58 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57, 58 and 60 are indefinite because it is unclear what type of analysis takes place or how the analysis takes place. It is also unclear what function is modulated and how the function is modulated. The metes and bounds of the claim(s) are not clearly set forth.

Claims 57 and 60 recite the limitation "modulates the cellular function regulated by the Fas receptor pathway" in lines 1-2 of claim 57. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

14. Claims 23 and 46 are objected to as being dependent upon a rejected base claim.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

DSR DSR
March 8, 1999